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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,157	03/25/2004	Keith E. Jasperson	151P9958US02	7387

54228 7590 11/04/2008

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POST OFFICE BOX 18455
MINNEAPOLIS, MN 55418

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ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
11/04/2008	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/809,157
Filing Date: March 25, 2004
Appellant(s): JASPERSON ET AL.

William D. Bauer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/2/2008 appealing from the Office action mailed 11/7/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/278769

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2001003370083	Hartlaub et al	11-2001

4731051	Fischell	3-1988
5069668	Boydman	12-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-13 rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al (2001/0037083). Hartlaub et al discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time ([0010, 0030, 0032, 0037-0042]), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time ([0010, 0030, 0032, 0037-0042]); said system determining a total dose over said specified period of time based on said basal rate and said interval rate ([0010, 0030, 0032, 0037-0042]); the system adjusting said

basal rate so that said total dose does not exceed said maximum dose ([0010, 0030, 0032, 0037-0042]); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step ([0010, 0030, 0032, 0037-0042], see also the Response to Arguments below). In reference to claims 2-12, see ([0010, 0030, 0032, 0037-0042], and 304).

In reference to claim 13, Hartlaub et al additionally discloses manually adjusting at least one of said plurality of interval rates ([0010, 0030, 0032, 0037-0042], see also the Response to Arguments below); said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step ([0010, 0030, 0032, 0037-0042]); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates ([0010, 0030, 0032, 0037-0042]).

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (4731051). Fischell discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional (see Figs and Summary), said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time (Summary), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time (Summary, Figs); said system determining a total dose over

said specified period of time based on said basal rate and said interval rate (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55); the system adjusting said basal rate so that said total dose does not exceed said maximum dose and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55). In reference to claims 2-12, see (Summary, Figs, especially Fig 21; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55).

In reference to claim 13, Fischell additionally discloses manually adjusting at least one of said plurality of interval rates; said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step; and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boydman (5069668) in view of Fischell. Boydman discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional (Abstract; Summary), said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time (Abstract, Summary; col 8, lns 50-col 10, lns 33), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time (Abstract, Summary; col 8, lns 50-col 10, lns 33); said system determining a total dose over said specified period of time based on said basal rate and said interval rate (Abstract, Summary; col 8, lns 50-col 10, lns 33); the system adjusting said basal rate so that said total dose does not exceed said maximum dose (Abstract, Summary; col 8, lns 50-col 10, lns 33); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step (Abstract, Summary; col 8, lns 50-col 10, lns 33). In reference to claims 2-12, see (Abstract, Summary; col 8, lns 50-col 10, lns 33 and col 13, lns 5-25). In reference to claim 13, Boydman additionally discloses manually adjusting at least one of said plurality of interval rates; said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step; and delivering said fluid medication in accordance with said basal rate as adjusted

in said adjusting step and said plurality of interval rates (Abstract, Summary; col 8, lns 50-col 10, lns 33).

However, Boydman fails to teach that the infusion system is implantable. Fischell teaches that it is known to have an implantable infusion set for the purpose of providing appropriate control means to an implantable pump to deliver medication to a site in the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the infusion controls for an infusion pump as taught by Boydman with the infusion control for an implantable infusion pump as taught by Fischell for the purpose of appropriate control means to an implantable pump to deliver medication to a site in the body.

(10) Response to Argument

Group I: Claims 1-7, 9-12, over Hartlaub et al '083

The appellant argues that Hartlaub et al does not disclose manually programming a maximum dose, a basal rate and a plurality of interval rates - individual ones of which correspond to individual ones of a plurality of time slots, determining a total dose based on basal and interval rates, and adjusting the basal rate so that the total dose does not exceed the maximum dose.

The Examiner notes that Hartlaub et al explicitly discloses manually programming a maximum dose ([0010, last 2 lns; 0029; 0030; 0032, last 3 lns]), a basal rate ([[0037 – base rate drug flow – the Examiner notes multiple rates may be programmed]) and a plurality of interval rates - individual ones of which correspond to

individual ones of a plurality of time slots ([0030 – bolus requests - the Examiner notes the requests may be programmed or entered manually over a given period of time and that the Appellant has not recited in the claims any limit and/or range to the specified period of time]), determining a total dose based on basal and interval rates ([0040, lns 6-10 – wherein the therapy program calculates the actual total dosage as the combination of the base rate and the number of bolus activations over the specified time period]), and adjusting the basal rate so that the total dose does not exceed the maximum dose ([0039, 0040, 0042 – wherein the therapy program explicitly discloses activating the lowest base rate to ensure that the total actual dose does not exceed the maximum dose limit]). The Examiner also notes that there is nothing in the present claim language that excludes reducing therapy deliver "at the last moment" as argued by the appellant. The appellant has not specified in the claims any range or period for the specified period of time. Additionally, see citations listed above in Grounds of Rejection.

Group II: Claim 13, over Hartlaub et al '083

The appellant argues that Hartlaub et al does not disclose a system adjusting a basal rate in accordance with a manual adjusting of at least one of the plurality of interval rates.

The Examiner incorporates the discussion with regard to Group I above hereby in its entirety and further notes that Hartlaub et al explicitly discloses a system adjusting a basal rate in accordance with a manual adjusting of at least one of the plurality of interval rates ([0039-0042 – wherein the interval rate is equivalent with the bolus

rate/dose in Hartlaub et al]). First, it is explicit that the system tracks the number of bolus activations requested by the patient over a specified period of time – the Examiner notes the bolus activations may also be preprogrammed for a specified period of time. Again, the Examiner notes the specified period of time has not been defined in the claims. Then, the system calculates the current total drug delivery and compares to the maximum drug delivery. If the dosage is approaching the maximum drug delivery, the system adjusts the basal rate to a lower rate and denies further bolus activation requests which is in its essence and adjustment of the interval rate (ie bolus activation).

Group I: Claims 1-12, over Fischell '051

The appellant argues that Fischell does not disclose setting a plurality of interval rates in addition to a basal rate, determining a total dose based on the basal and interval rates, and adjusting the basal rate based on a comparison of the total dose with the maximum dose.

The Examiner notes that Fischell explicitly discloses setting a plurality of interval rates (Supplemental Prescription Schedule – Fig 21 – wherein multiple supplemental prescription schedules may be programmed) in addition to a basal rate (Basal Prescription Schedule – Fig 21 – wherein multiple basal prescription schedules may be programmed), determining a total dose based on the basal and interval rates (integral dose limits – the device has two – a 3 hr limit and a 24 hr limit – again the Appellant has not defined the specified period of time in the claims), and adjusting the basal rate based on a comparison of the total dose with the maximum dose (Fig 21; col 2, lns 67-col 3, lns 14; col 7, lns 10-17; col 16, lns 54-col 17, lns 26; col 20, lns 58-65; and col 30,

lns 34-col 31, lns 63). Essentially, the device counts the total dosage that has been delivered and compares the total dosage to the set maximum limit and based upon the prescription schedule and basal schedules adjust dosage from either or both of the prescription and basal schedules to prevent over dosage. This can occur in a 3 hr rolling window or over a 24 hr window. The appellant has not specified a required time periods or range of time to which the specified period of time in the claim refers. Additionally, see citations listed above in Grounds of Rejection.

Group II: Claim 13, over Fischell '051

The appellant argues that Fischell does not additionally disclose manually adjusting one of the interval rate and the system adjusting the basal rate over that period of time based on the adjustment to the interval rates.

The Examiner incorporates the discussion with regard to Group I above hereby in its entirety and further notes that Fischell explicitly discloses manually adjusting one of the interval rate and the system adjusting the basal rate over that period of time based on the adjustment to the interval rates (Fig 21; col 2, lns 67-col 3, lns 14; col 7, lns 10-17; col 16, lns 54-col 17, lns 26; col 20, lns 58-65; and col 30, lns 34-col 31, lns 63). When the integral dose limit on either a 3 hr or 24 hr scale calculates that based upon the total delivered dosage and current supplemental and basal prescription schedules that there will be an over dosage if the device continues to deliver drug at the requested rate and time via the supplemental and basal prescription, the device adjusts the supplemental and/or basal prescriptions schedules to prevent over dosing the patient. This adjustment is specifically over a period of time and the basal rate is adjusted based

upon what the rate of dosage is from the supplemental schedules. Further, both schedules can be prevented from dosing drug to the patient at the same time over the same time period.

Group I: Claim 1-10, 12, over Boydman '688 in view of Fischell '051

The appellant argues that Boydman does not disclose setting a plurality of interval rates in addition to a basal rate, determining a total dose over the specified period of time based on the basal and interval rates, and adjusting the basal rate based upon comparing the total dose with the maximum dose. Additionally, the Appellant argues the combination under KSR.

First, the Examiner notes that Boydman explicitly discloses setting a plurality of interval rates (on demand or interval dosing; col 4, lns 19-26) in addition to a basal rate (current rate dosing or background dosing; col 4, lns25-26), determining a total dose over the specified period of time based on the basal and interval rates (col 5, lns 10-29), and adjusting the basal rate based upon comparing the total dose with the maximum dose (discussion of rate adjustment factor; col 10 lns 10-32). Additionally, the Examiner notes that the Appellant has not specified in the claims a range or limit for the specified period of time. Additionally, see citations listed above in Grounds of Rejection.

Secondly, the Examiner notes that the Examiner did not proposed the combination of Boydman and Fischell on KSR guidelines. The proposed combination is simply to say that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of infusion as taught by Boydman set in an implantable device, such as one disclosed by Fischell.

Group II: Claim 13, over Boydman '688 in view of Fischell '051

The appellant argues that Boydman additionally does not disclose the system adjusting at least one of the plurality of the interval rates and adjusting the basal rate in accordance with the plurality of interval rates as adjusted. Additionally, the Appellant argues the combination under KSR.

First, the Examiner incorporates the discussion with regard to Group I above hereby in its entirety and further notes that Fischell explicitly discloses the system adjusting at least one of the plurality of the interval rates and adjusting the basal rate in accordance with the plurality of interval rates as adjusted (col 5). The Examiner notes that the on demand doses are only administered if they can be given without violation of a preset maximum dosage limit and a specified amount of time has transpired between basal or current rate dosages. The interval rates are not delivered to prevent overdosing. Further, the current rate dosages are modified based upon the data from the demand dosage. Thus, if the maximum drug limit is being approached, the demand dosages will be denied and the current rate dosages will be adjusted (by the rate adjustment factor) to prevent over dosing.

Secondly, the Examiner notes that the Examiner did not proposed the combination of Boydman and Fischell on KSR guidelines. The proposed combination is simply to say that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of infusion as taught by Boydman set in an implantable device, such as one disclosed by Fischell.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew M Gilbert/

Examiner, Art Unit 3767

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